Amendments to the claims

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (Currently Amended): A sustained release oral solid dosage form ~~for absorption of a therapeutically active medicament in the gastrointestinal tract~~ for providing an effective dose of a medicament having a solubility of less than about 10 g/l over a 24 hour period, comprising:

an effective amount of a medicament having a solubility of less than about 10 g/l to render a therapeutic effect;

a sustained release excipient comprising a gelling agent comprising a heteropolysaccharide gum and a homopolysaccharide gum capable of cross-linking said heteropolysaccharide gum when exposed to an environmental fluid, the ratio of said heteropolysaccharide gum to said homopolysaccharide gum being from about 1:3 to about 3:1; an inert pharmaceutical diluent; ~~selected from the group consisting of monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, the ratio of said inert diluent to said gelling agent being from about 1:8 to about 8:1~~; ~~and~~ a pharmaceutically acceptable cationic cross-linking agent capable of crosslinking with said gelling agent and increasing the gel strength when the dosage form is exposed to an environmental fluid. ~~; the ratio of said medicament to said gelling agent being from about 1:3 to about 1:8, said dosage form providing a sustained release of said medicament when exposed to an environmental fluid~~ said excipient being granulated with a hydrophobic material prior to incorporation of said medicament, said hydrophobic material being included in an amount effective to slow the hydration of said gelling agent when exposed to environmental fluid.

Claim 2. (Original): The oral solid dosage form of claim 1, wherein said heteropolysaccharide gum comprises xanthan gum and said homopolysaccharide gum comprises locust bean gum.

Claim 3. (Original): The oral solid dosage form of claim 2, wherein said cationic crosslinking agent comprises from about 0.5 to about 16 percent of said formulation, by weight.

Claim 4-5 (Cancelled)

Claim 6. (Original): The oral solid dosage form of claim 1, wherein said medicament is selected from the group consisting of nifedipine, nimodipine, nivadipine, nitrendipine, nisolidipine, niludipine, nicardipine and felodipine.

Claim 7. (Currently Amended): The oral solid dosage form of claim 1, wherein said cationic crosslinking agent ~~comprises an~~ is selected from the group consisting of an alkali metal sulfate, an alkali metal chloride, an alkali metal borate, an alkali metal bromide, an alkali metal citrate, an alkali metal lactate, ~~or~~ an alkaline earth metal sulfate, an alkaline earth metal chloride, an alkaline earth metal borate, an alkaline earth metal bromide, an alkaline earth metal citrate, an alkaline earth metal acetate, ~~or~~ an alkaline earth metal lactate, and mixtures thereof.

Claim 8. (Currently Amended): The oral solid dosage form of claim 1, wherein said cationic cross-linking agent comprises calcium sulfate, and said hydrophobic material is ethylcellulose.

Claim 9-81 (Canceled)

Claim 82 (New): The dosage form of claim 1, wherein the ratio of said medicament to said gelling agent is from about 1:3 to about 1:8.

Claim 83 (New): The dosage form of claim 1, wherein the pharmaceutically acceptable hydrophobic material is included in the sustained release excipient in an amount from about 1 to about 20 percent by weight.

Claim 84 (New): The dosage form of claim 1, wherein the ratio of said inert diluent to said gelling agent is from about 1:8 to about 8:1.

Claim 85 (New): A method of preparing a sustained release excipient comprising:

dry blending

a gelling agent,

an inert pharmaceutically acceptable diluent selected from the group consisting of a monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, and

a pharmaceutically acceptable cationic crosslinking agent capable of cross-linking with said gelling agent when exposed to an environmental fluid to increase the gel strength,

wherein said gelling agent is from about 10 to about 99 percent by weight of the excipient, said diluent is from about 0 to about 89 percent by weight, said cationic cross-linking agent is from about 1 to about 20 by weight of the excipient.

Claim 86 (New): The method of claim 85, further comprising:

(i) adding water to the dry blend to form a mixture;

(ii) granulating the mixture of step (i);

(iii) drying the mixture of step (ii);

(iv) milling the mixture of step (iii).

Claim 87 (New): A method of preparing a sustained release excipient comprising:

(i) dry blending

a gelling agent,

an inert pharmaceutically acceptable diluent selected from the group consisting of a monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, and

a pharmaceutically acceptable cationic crosslinking agent capable of cross-linking with said gelling agent when exposed to an environmental fluid to increase the gel strength,

to form an excipient blend;

wherein said gelling agent is from about 10 to about 99 percent by weight of said excipient blend, said diluent is from about 0 to about 89 percent by weight of said excipient

blend, said cationic cross-linking agent is from about 1 to about 20 by weight of said excipient blend, and

(ii) granulating said excipient blend with a solution of a hydrophobic material, said hydrophobic material being included in an amount effective to slow the hydration of the gelling agent without disrupting the hydrophillic matrix.

Claim 88 (New): The method of claim 87, wherein, prior to step (ii),

the excipient blend of step (i) is wet granulated to form a mixture.

Claim 89 (New): A method of preparing a sustained release excipient comprising:

(i) dry blending

a gelling agent,

an inert pharmaceutically acceptable diluent selected from the group consisting of a monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, and

a pharmaceutically acceptable cationic crosslinking agent capable of cross-linking with said gelling agent when exposed to an environmental fluid;

wherein said gelling agent includes a heteropolysaccharide and a homopolysaccharide gum, wherein the ratio of said heteropolysaccharide gum to said homopolysaccharide gum in the gelling agent is from about 1:3 to about 3:1, and wherein the ratio of said inert diluent to said gelling agent is from about 1:8 to about 8:1.

Claim 90 (New): The method of claim 89, further comprising:

(i) adding water to the dry blend to form a mixture;

(ii) granulating the mixture of step (i);

(iii) drying the mixture of step (ii);

(iv) milling the mixture of step (iii).

Claim 91 (New): A method of preparing an oral solid dosage form comprising:

(i) dry blending

a gelling agent comprising a heteropolysaccharide gum and a homopolysaccharide gum capable of cross-linking said heteropolysaccharide gum when exposed to an environmental fluid,

an inert pharmaceutical diluent selected from the group consisting of monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, and

a pharmaceutically acceptable cationic cross-linking agent capable of crosslinking with said gelling agent and increasing the gel strength when the dosage form is exposed to an environmental fluid;

(ii) adding water to the dry blend of step (i) to form a mixture;

(iii) granulating the mixture of step (ii);

(iv) drying the mixture of step (iii);

(v) milling the mixture of step (iv);

(vi) adding to the milled mixture of step (v) an effective amount of a medicament having a solubility of less than about 10 g/l to render a therapeutic effect;

wherein the ratio of said heteropolysaccharide gum to said homopolysaccharide gum is from about 1:3 to about 3:1; wherein the ratio of said inert diluent to said gelling agent is from about 1:8 to about 8:1; and the ratio of said medicament to said gelling agent is from about 1:3 to about 1:8.

Claim 92 (New): A method of preparing an oral solid dosage form comprising:

(i) dry blending

a gelling agent comprising a heteropolysaccharide gum and a homopolysaccharide gum capable of cross-linking said heteropolysaccharide gum when exposed to an environmental fluid,

an inert pharmaceutical diluent selected from the group consisting of monosaccharide, a disaccharide, a polyhydric alcohol, and mixtures thereof, and

a pharmaceutically acceptable cationic cross-linking agent capable of crosslinking with said gelling agent and increasing the gel strength when the dosage form is exposed to an environmental fluid;

(ii) adding water to the dry blend of step (i) to form a mixture;

(iii) granulating the mixture of step (ii);

(iv) drying the mixture of step (iii);

(v) milling the mixture of step (iv);

(vi) granulating the mixture of step (v) with a hydrophobic material;

(vii) adding an effective amount of a medicament having a solubility of less than about 10 g/l, to render a therapeutic effect, to the mixture of step (vi);

wherein the ratio of said heteropolysaccharide gum to said homopolysaccharide gum is from about 1:3 to about 3:1; wherein the ratio of said inert diluent to said gelling agent is from about 1:8 to about 8:1; and the ratio of said medicament to said gelling agent is from about 1:3 to about 1:8.

Claim 93 (New): A method of preparing an oral tablet comprising:

(i) dry blending

a gelling agent comprising xanthan gum and locust bean gum,

a pharmaceutically acceptable cationic cross-linking agent capable of cross-linking with said gelling agent and increasing the gel strength when the dosage form is exposed to environmental fluid, and

an inert pharmaceutical diluent;

(ii) adding a medicament having a solubility of less than about 10 g/l;

wherein the ratio of said xanthan gum to said locust bean gum in the gelling agent is from about 1:3 to about 3:1; wherein the ratio of said inert diluent to said gelling agent being from about 1:8 to about 8:1.

Claim 94 (New): A method of preparing an oral tablet comprising:

(i) dry blending

a gelling agent comprising xanthan gum and locust bean gum,

a pharmaceutically acceptable cationic cross-linking agent capable of cross-linking with said gelling agent and increasing the gel strength when the dosage form is exposed to environmental fluid, and

an inert pharmaceutical diluent;

(ii) adding an effective amount of a medicament having a solubility of less than about 10 g/l to form a mixture;

(iii) compressing the mixture to form a tablet;

(iv) coating said tablet with a hydrophobic material selected from the group consisting of an alkylcellulose, a hydrophobic cellulosic material, a copolymer of acrylic and methacrylic acid esters, waxes, shellac, zein, hydrogenated vegetable oils, and mixtures of any of the foregoing; wherein said tablet is coated with said hydrophobic coating to a weight gain from about 1 to about 20 percent of the total weight of said tablet.

Claim 95 (New): The method of claim 94 further comprising wet granulating the mixture of step (i).

Claim 96 (New): A method of preparing an oral tablet comprising:

(i) dry blending

a gelling agent comprising xanthan gum and locust bean gum,

a pharmaceutically acceptable cationic cross-linking agent capable of cross-linking with said gelling agent and increasing the gel strength when the dosage form is exposed to environmental fluid, and

an inert pharmaceutical diluent;

(ii) adding a medicament having a solubility of less than about 10 g/l to form a mixture;

wherein the ratio of xanthan gum to locust bean gum is from about 1:3 to about 3:1; wherein the ratio of said inert diluent to said gelling agent being from about 1:8 to about 8:1; and the ratio of said medicament to said gelling agent being from about 1:3 to about 1:8.

(iii) tabletting the mixture.

Claim 97 (New): A method of preparing a sustained release composition comprising preparing a matrix comprising:

(i) mixing

a gelling agent, an inert pharmaceutical diluent, and

a pharmaceutically acceptable cationic cross-linking agent capable of cross-linking with said gelling agent and increasing the gel strength of said gelling agent when the dosage form is exposed to an environmental fluid;

(ii) adding an effective amount of a medicament having a solubility of less than about 10 g/l, to render a therapeutic effect.